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I. INTRODUCTION

Gene splicing,[1] an emergent exploratory tool, enables scientists to catalogue the 100,000 genes found in a human cell.[2] By mapping genes on chromosomes, scientists may be able to compile the data necessary to attempt therapeutic cures of human genetic disorders.[3] Gene splicing may also facilitate economically viable production of insulin,[4] interferon[5] and other human medications,[6] as well

1. Gene splicing, also known as genetic engineering or recombinant DNA, provides the basis for designing specialized bacteria or other organisms such as viruses, fungi or tissue culture cells which will produce useful gene products or have useful functions as mutant cells. Associated applications utilize cloned genes or gene fragments as diagnostics in medical genetics. Boyer, *The Age of Molecular Biology*, 7 APLA Q. J. 185, 189 (1979). Genetic engineering technology makes it possible for a researcher to isolate a single gene from an organism's total DNA, to recombine it with a carrier molecule of DNA and to introduce the recombinant DNA into a bacterial cell. Anderson & Diaumakos, *Genetic Engineering in Mammalian Cells*, SCI. AM., July, 1981, at 121. Different kinds of cells make different proteins, as instructed by the DNA encoded in the genes of the cells. Developments in molecular biology enable scientists to alter the instructions in bacterial cells, thereby designing bacteria that can synthesize nonbacterial proteins. The bacteria are "recombinants." If the recombinant has an important biomedical application, "a culture of the recombinant bacteria, which can be grown easily and at a low cost, will serve as an efficient factory for producing" that recombinant. Gilbert & Villa-Kamaroff, *Useful Proteins from Recombinant Bacteria*, SCI. AM., Apr., 1980, at 74. Developments in genetic engineering techniques afford a researcher the means by which to "isolate one of the million-odd genes of an animal cell, to fuse that gene with part of a bacterial gene and to insert the combination into bacteria. As those bacteria multiply they make millions of copies of their own genes and of the animal gene inserted among them." *Id. See also* Sun, *More Progress on Gene Transfer*, 213 SCI. 996 (1981) [hereinafter cited as Sun]. For a discussion of recent developments involving biotechnology and animal genetics, *see* L. F. CAVALIERI, THE DOUBLE-EDGED HELIX (1981).

2. Sun, *supra* note 1, at 997. If a gene of unknown function is inserted into bacteria, it can act as a probe that allows scientists to examine its effect. "Recombinant DNA research has revealed that genes are fungible; animal genes function perfectly well within bacteria and bacterial genes within animal cells, confirming the unity of nature." Singer, *Recombinant DNA Revisited*, 209 SCI. 1318 (1980). For an historical examination of the changing concept of the gene, see Chanibou, *Split Genes*, SCI. AM., May, 1981, at 60 [hereinafter cited as Chanibou].

3. Chanibou, *supra* note 2, at 61. More than 2000 human diseases are caused by a single abnormality in any particular gene which embodies the genetic blueprint for making a single protein. *Id.* Even though the abnormality forms only a minute percentage of one gene among the many thousands needed to create a human being, that small abnormality can produce large-scale deleterious effects. Possible effects from such genetic abnormality include physical deformity, hormone problems, heart failure, poorly-clotting blood and mental retardation. *Id. See also* Marx, *Genes That Control Development*, 213 SCI. 1485 (1981) (describing the application of recombinant DNA techniques to the Mediterranean fruit fly in order to examine the genes that control development of higher organisms); and *Inadmissible Evidence*, SCI. AM., Dec., 1981, at 78 (describing advances in cancer research via genetic engineering methods).

4. Insulin is the hormone that enables the body to burn sugar for energy. Of the 1.8 million diabetics

as improving agricultural output. Through gene splicing, scientists may be able to develop crops which provide their own fertilizer and which can grow in minerally deficient soils.[7] Like most emergent technology, genetic engineering has scientific, economic and legal implications.

Scientists began genetic engineering ("recombinant DNA") research at academic centers. University scientists traditionally engage in pure research, regardless of the prospects of commercial success.[8] This research has now spread to the commercial world as well.[9] As large corporations have recognized the potential for profit through genetic engineering,[10] scientists have begun to serve as corpo-

in the United States using insulin, 5% suffer allergic reactions from the natural insulin extracted from animal pancreases. Chanibou, *supra* note 2, at 62. Insulin synthesized by recombinant DNA techniques results in an unlimited supply of non-allergic human insulin. *See generally* R. W. OLD & S. B. PRIMROSE, PRINCIPLES OF GENETIC ENGINEERING: AN INTRODUCTION TO GENETIC ENGINEERING (1980); J. MORGAN & W. J. WHELAN, RECOMBINANT DNA AND GENETIC EXPERIMENTATION (1979); M. V. VOLKENSTEIN, MOLECULAR BIOPHYSICS (1977).

5. Interferon, a protein regularly produced by the body, is a virus-fighting agent of unmatched strength but problematic power. M. EDELHART & J. LINDENMANN, INTERFERON: THE NEW HOPE FOR CANCER 17 (1981). Researchers have shown interferon to be potently effective against any virus. *Id.* Although there are currently eight persons in the world receiving treatment of genetically engineered interferon, scientists must better understand interferon's causes and effects before marketing it. Traditional methods of producing interferon are costly; one pound of the substance is worth $10 billion. *Id.* Natural interferon treatment costs approximately $150 per day, but synthetic production could lower the price to $1 per day. *Id.* These financial considerations have not been overlooked by investors, who have financially spurred interferon research. *Id.* Interferon is currently being tested at the Medical Research Council's Common Cold Unit in Salisbury, England as a preventative of rhinovirus infection, one of the causes of the common cold. Walgate, *Interferon Used At Last,* 295 NATURE 273 (1982).

6. Additional medications which may be biotechnologically synthesized include human growth hormone (used to treat dwarfism, and traditionally only available in limited quantities from pituitary glands of cadavers); urokinase (which dissolves blood clots); thymosin alpha-I (a hormone for treatment of brain and lung cancer); and beta-endorphin (the brain's painkiller). Chanibou, *supra* note 2, at 63.

7. Demain & Solomon, *Industrial Microbiology,* SCI. AM., Sept., 1981, at 67. Recent advances in molecular biology have generated interest about the prospective application of novel microbiological techniques in a wide range of industrial roles. Genetically engineered soybean strains may boost by 10% the yield of U.S. soybean, a crop which is worth about $16 billion annually. *Biotechnology Boom Reaches Agriculture,* 213 SCI. 1339 (1981). Other biotechnological affects on the food chain involve soil improvement and task-specific enzymes. *Id. See generally* Blair, *Test-Tube Gardens,* 3 SCI. 82, April, 1982, at 70; SCI. AM., Sept., 1981 (special issue on industrial microbiology).

8. Society looks to the technical community for warning, guidance and protection. Whether the needs be informational, such as effects of cylcamates or DDT, or goal-oriented, such as the space exploration program, the public has given special status to highly-trained people like scientists. Society invests in the training and professional development of scientists, researchers and engineers by providing substantial public subsidy of academic and research facilities. The professions may choose the direction of research, enforce the quality of work and direct the allocation of public funds within their subject area. Concomitantly, society places certain trusts and responsibilities in the professions. The professions, in turn, are obliged to govern themselves and are committed to the service of society. W.LOWRANCE, OF ACCEPTABLE RISK: SCIENCE AND THE DETERMINATION OF SAFETY 120-26 (1976). *See also* Jasanoll & Nelkin, *Science, Technology, and the Fruits of Judicial Competence.* 214 SCI. 1211 (1981) (discussing the resolution of technological controversies in the judicial arena).

9. *The Business of Research,* SCI. AM., Feb., 1982, at 70. The article describes the financial potential of genetic engineering, its consequent attraction to investors, and the financial relationships between corporations and educational institutions.

10. Since 1978, at least 40 new bioengineering companies have been formed. Weber, *A New Industry*

rate advisors for companies engaging in such research. Many of these scientists are now involved in goal-oriented experimentation in conjunction with bioengineering firms.[11]

Springs to Life, VENTURE, May, 1981, at 88. Commentators estimate that 70 to 100 new bioengineering companies are now in existence. Rosenberg, *The Promise of Profits in Genetics,* Boston Globe, Sept. 14, 1981, at 1, col. 1. A representative of E. F. Hutton estimates that investment of private capital for genetic research will involve $1.9 billion by 1985. BUS. WEEK, June 30, 1980, at 48, col. 2. One example of the financial significance of this investment is the case of Genentech, Inc. When the corporation entered the over-the-counter market with a $36 million stock offering in October, 1980, its opening price of $35 per share rose in minutes to $89. Many similar companies received such unprecedented initial responses. Some analysts predict, however, that those responses will not continue, for at least three reasons: Genentech stock was offered during a particularly bullish market; Genentech was the first biotechnology company to go public; and Genentech kept the number of issues relatively low at 1 million shares. Sun, *Genentech: Is Its Glamor Gone?,* 211 SCI. 262 (1981).

The collapse of another $40 million biotechnology venture has prompted its underwriter, E. F. Hutton, to offer biotechnology tax shelters. The original biotechnology venture, DNA Science, was to have branches in Israel, Ohio and California. The company also employed a Nobel prizewinner as a staff member. The original structure of DNA Science was similar to that of a holding company; small subsidiary companies established near major universities would conduct its business to accommodate specific research projects. The subsidiary companies would market the products resulting from the projects, and the researching scientist would maintain an equity interest in the venture. The capital acquisition plan unraveled when corporate investors (Allied Chemical and Johnson & Johnson) wanted proprietary rights to DNA Science's products. E. F. Hutton is now attempting to restructure an organization to take advantage of the newly enacted 25% tax credit for incremental investments in research and development. If successful, the biotechnology tax shelters will resemble investments made in oil and gas drilling, movie productions, real estate and race horses. Norman, *First Casualty in the Biotechnology Derby,* 213 SCI. 1087-90 (1981). *See also* Wade, *How to Keep Your Shirt — If You Put It in Genes,* 213 SCI. 26 (1981).

11. *See* note 10 *supra;* Sherman, *MIT Weighs Biomedical Affiliate OK,* Boston Globe, October 1, 1981, at 28, col. 1.

Potential conflicts of interest arise when academicians engage in pure research and at the same time serve in an advisory capacity to commercial venture. Although some observers regard these relationships as potentially problematic, most observers agree that society benefits from the commercial application of academic research. *The Business of Research,* SCI. AM., Feb., 1982, at 70 [hereinafter cited as *The Business of Research*]. Several concerns exist regarding an academic researcher serving in the management of a company whose business is closely related to his research, such as: the possibility that basic research will be subsumed by applied research offering financial profit, rather than fundamental insights; the likelihood that corporate secrecy will hamper the relatively free exchange of information in the academic community; and the chance that the nature of advanced teaching will focus students solely on financially rewarding subjects. *Id. See Can Even Mere Knowledge Be A Threat?,* 295 NATURE 269 (1982) (addressing the issues when conflict arises between academic freedom and national security). *See also Making Private Interests Public,* 295 SCI. 357 (1982) (describing new regulations proposed by California's Fair Political Practices Committee which would require scientists to report potential conflicts of interest).

The practice of faculty members serving as consultants to industry is not without precedent. Generally, chemistry and engineering firms have adopted such relationships without adverse effects on research. For instance, developments in lasers and semi-conductors were marked by the combined efforts of businesses and universities. Not only do many of the high technology firms owe their vitality to the participation of university faculty, many universities have in the past utilized patents on innovations by their faculty as a source of revenue. *The Business of Research, supra,* at 70. For instance, Indiana University receives substantial income from its patent on the fluoride solution used in dentistry and the University of Florida profited from its patent on the beverage formula sold as Gatorade. *Id.* For a report on a patent dispute between two groups of researchers, see Wade, *La Jolla Biologists Troubled by the Midas Factor,* 213 SCI. 623, 628 (1981) [hereinafter cited as Wade].

Universities with coherent patent and licensing strategies will not lose the benefits of research accomplished in their laboratories. For instance, Stanford University is expecting applications from 200

Patent law in Great Britain and the United States provides an officially sanctioned incentive system which encourages disclosure to the public of new and useful inventions.[12] The patentee exchanges full and complete disclosure of how to make and use the claimed invention for the court-protected right to exclude others from making, using or selling the claimed invention for the statutory period.[13] A patentee would be reluctant to invest time and money in an invention without assurance of protection from easy and inexpensive duplication of his invention by others. The existence of a protective patent system has the effect of encouraging scientists to proceed with inventions for which they can claim exclusive rights. Thus, the effect of the patent system is to assure an open marketplace for technological ideas.[14]

By providing an incentive for developing and marketing such discoveries, the patent systems in Great Britain and the United States play an integral role in the development of biotechnology in their respective nations.[15] Analysis of recent legal developments affecting genetic engineering provides insight into what is, and what should be, the role of patent rights in developing and applying this technology. The British patent system is currently undergoing general revision due to the enactment of Patents Act 1977.[16] In the United States, the patentability of genetically engineered organisms was the focus of the Supreme Court in *Diamond v. Chakrabarty*.[17] In *Chakrabarty*, the Supreme Court determined that the claimant's microorganism was patentable under the PatentAct of 1952.[18]

One aspect of biotechnology with which British and U.S. patent law has not yet addressed is the synthesis of a virus with which to infect a bacterium. Physiologically, a virus is radically different from a microorganism, and presents issues that distinguish its patentability from that of a microorganism.[19] Since neither

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firms for the licensing of its patented gene splicing technology. Holden, *Briefing*, 213 SCI. 1089 (1981). The nonexclusive license is available to any commercial user of the process for an initial fee of $10,000 plus an annual fee of $10,000. *Id.* The royalty rate will be 1% on net sales up to $5 million, and 0.5% on sales above $10 million annually. *Id.* Annual revenues could reach $1 million in four or five years. *Id.*

Often decades pass before scientific discoveries leave the laboratory and find everyday application. "Vannevar Bush's quip that the difference between basic and applied sciences is 'about 20 years' may still be true in chemistry or engineering. With molecular biology, however, the gap often appears to have shrunk to a matter of weeks." Wade, *supra*, at 628. Beneficial research techniques spawned by recombinant DNA "were unimaginable even five years ago," states one observer, Maxine Singer of the National Cancer Institute. Singer, *Recombinant DNA Revisited*, 209 SCI. 1318 (1980). "And molecular biologists alone did not accomplish all this. They had unprecedented support from enlightened societies and governments. It has been a joint venture, and we should celebrate together." *Id.*

12. Richey, *Implications of the Plant Patent Act for the Patentability of Microorganisms*, 39 MD. L. REV. 376, 376 (1979) [hereinafter cited as Richey].

13. *Id.*

14. *Id.* For the consumer, the system fosters an ever-widening choice of goods and services. *Id.*

15. *See* notes 12-15 and accompanying text *supra*.

16. Patents Act, 1977, ch. 37, §§ 1-4.

17. 447 U.S. 303 (1980).

18. *Id.* The Patent Act of 1952, 35 U.S.C. §§ 101-103 (1970).

19. A microorganism is a living entity with a specific metabolism and capable of reproduction. A

Great Britain nor the United States has instituted a patent claim for a synthesized virus, this Comment analyzes the current trend of biotechnology patent law in Great Britain and the United States through the use of a hypothetical patent claim for such a virus. Specifically, the author examines the statutory provisions of patentability in Great Britain and in the United States, comparing the means by which the two patent systems have faced recent advances in biotechnology. The author presents the historical background presaging Great Britain's enactment of the Patents Act 1977 and discusses the three conditions for patentability under the Patents Act 1977: novelty, inventive step and industrial application. The author then reviews the policies underlying U.S. patent law and the requirements for patentability under the Patent Act of 1952 in light of the *Chakrabarty* decision. By examining the British and American patent systems in terms of a hypothetical claim for a synthesized virus, the author concludes that both patent systems broadly afford patentability for such emergent technology.

II. BIOTECHNOLOGY PATENT LAW IN GREAT BRITAIN

A. *Background of the British Patent Law System*

Great Britain has long recognized the need for a patent system.[20] However, rapid advances in technology during the last decade and the resulting acceleration of scientific invention[21] caused British laws relating to the protection of

virus, however, is incapable of performing the normal functions of life (such as reproduction) unless it is sustained by a living, "host" cell. This total dependency of viruses is called obligatory parasitism. Furthermore, unlike organisms, viruses contain no cellular structure. These unique characteristics have caused many biologists to classify viruses as somewhere between the living and non-living. *See generally* J. D. EBERT, A. G. LOEWY, R. S. MILLER, H. A. SCHNEIDERMAN, BIOLOGY (1973) [hereinafter cited as EBERT]; M. J. PELCZAR, JR., R. D. REID, E. C. S. CHAN, MICROBIOLOGY (1977) [hereinafter cited as PELCZAR].

Viruses are chemically definable compositions, and can propagate only in certain living cells. One researcher described viruses as:

> the elegantly symmetrical particulate structures composed essentially of a molecule of nucleic acid encapsulated in a protein coat. They can exist outside the cell, but there they are inert. Once inserted into a cell, however, their nucleic acid (RNA or DNA) reprograms the cell's metabolic apparatus to the service of the virus; the nucleic acid replicates and is encapsulated, in the process destroying the cell and releasing a new crop of virus particles.

Novick, *Plasmids,* 243 SCI. AM., Dec., 1980, at 102. A great deal of time and effort has been spent on research involving the relationship of viruses and cancer. Investigators are discovering that gene alterations contribute to the development of many cancers. Using gene transferring techniques, "researchers are gaining the ability to isolate, clone and study in detail transforming genes from cancers that have arisen spontaneously or been induced by chemicals." Marx, *Gene Transfer Yields Cancer Clues,* 215 SCI. 955, 955 (1982).

20. McFarlane, *A New Patent Law for the United Kingdom,* Scots Law Times, Dec. 18, 1977, at 255-68, col. 2. [hereinafter cited as McFarlane].

21. *Id.* Great Britain has begun to establish science parks, which link businesses with universities, in much the same manner as found in similar establishments in the United States. Cross, *Science in the Park,* 93 NEW SCIENTIST 432 (1982). These parks produced beneficial results for both business and academia; the university earned money and students were exposed to the business aspects of commercially developing their discoveries. *Id.* In both Great Britain and the United States, parks initially focused on industries such as computer manufacturers, software companies, electronics concerns and the research divisions of pharmaceutical firms. More recently, science parks have engaged in genetic engineering. *Id.*

industrial and intellectual property rights to become outdated. Existing law[22] — The Patents Act 1949 and The Copyright Act 1956 — lacked sufficient flexibility to deal with the new concepts for which inventors sought patent protection.[23] This inflexibility was apparent in cases of new technologies, such as software data processing, which had fundamentally altered previously existing processes.[24]

The quarter century between Great Britain's last two patents acts was a period of great activity in the industrial property field, marked by a series of international conventions and by new patent laws in many countries.[25] Patent systems existing in Great Britain and elsewhere were unable to handle efficiently the worldwide technology explosion in which technological innovations were being applied to old handcraft industries.[26] The advances in areas such as farming, home equipment and wholesale and retail trading became increasingly complex and transnational in character, as did developments in communications, computers and other advanced technology.

The scope of these technical innovations led to two types of problems for the existing patent systems. The first problem was that the number of applications and the complexity of potential patents increased to such an extent as to overburden the system.[27] The second problem which emerged in recent years was the insular nature of the patent systems. Each nation had developed its own patent laws with little regard to the corresponding laws of other nations. As a result, procedural and substantive law varied from one country to another.[28]

The British government recently announced its decision to boost biotechnology research in the universities. Carlton, *And British Universities Grasp the Biotechnology Nettle,* 93 NEW SCIENTIST 213 (1982). A scientist in the Department of Industry suggests coordinating research and development to make the most of scarce resources and to ensure that Great Britain does not fall behind in the biotechnology race. Biotechnology will be the subject of the next investigation of the House of Commons Select Committee for Education, Science and Arts, in order to consider government policy on biotechnology, research, development and application. *Id.*

22. The Patents Act, 1949, 12, 13 & 14 Geo. 6, ch. 87; The Copyright Act, 1956, 4 & 5 Eliz. 2, ch. 47.

23. McFarlane, *supra* note 20, at 265. The drafters of the original patent legislation did not foresee the extent to which innovation would outstrip traditional notions of invention and patent protection. *Id. See also* Gallagher-Daggitt, *Innovation in Perspective,* 93 NEW SCIENTIST 9-19 (1982) [hereinafter cited as Gallagher-Daggitt] (presenting a series of articles describing Britain's general approach to industrial research and development).

24. Gallagher-Daggitt, *supra* note 23, at 9-10. *See also* notes 138, 141 & 142 and accompanying text *infra.*

25. Michaels, *The British Patents Act of 1977,* 13 INT'L LAW. 667, 669 (1979) [hereinafter cited as Michaels]. Nations which enacted new patent laws in the last 15 years include Denmark, Finland, France, Germany, Japan, the Netherlands, Norway, Sweden and Switzerland. *Id.* For a synopsis of these patent systems, see *id.* at 668-71.

26. *Id.* at 668.

27. *Id.* Because the examining patent offices could not keep pace with the volume and complexity of the applications filed, the patentees and industries were not aware of what they would be prohibited from patenting. *Id.* The British Patent Office was analyzed by a Parliamentary committee in 1970 as being "in arrears of some 47,000 unexamined specifications," which represented about one year's work. THE BANKS' COMMITTEE, THE BRITISH PATENT SYSTEM: REPORT OF THE COMMITTEE TO EXAMINE THE PATENT SYSTEM AND PATENT LAW, CMD. 4407, at 24-26, 95-99 (1970) [hereinafter cited as BANKS' COMMITTEE].

28. Michaels, *supra* note 25, at 668. The growth in transnational trade and exchange of technology

The twin goals of reducing the unwieldy search burden on examining patent offices and of introducing transnational patent law uniformity dominated the developments of patent law in Great Britain and abroad for the last twenty-five years.[29] In 1967 Parliament appointed a committee, known as the Banks' Committee in honor of its chairman, which reviewed the British patent system and outlined suggestions for reform with a view toward international collaboration. Three years later the Committee issued its report to Parliament.[30] In April 1975, the British government issued a White Paper setting forth a plan to frame new patent legislation.[31] The Paper closely followed the Banks' Committee Report and suggested international patent collaboration.[32]

Legal developments in the area of patent law in other nations also influenced British patent law reform. Specifically, several other nations recently had adopted more effective protection for emergent technology.[33] As a result, Great

highlighted the differing patent systems. Applicants seeking patent protection in various nations faced different application procedures and standards. These separate patent systems entailed a great duplication of effort by the patentee and the examining patent office. Furthermore, the applicant faced different definitions of the invention and novelty requirements. *Id.*

29. *Id.* For an overview of the various conventions, conferences and statutory amendments preceding 1977, see *id.* at 668-71.

30. BANKS' COMMITTEE, *supra* note 27, at 24-26.

31. The Department of Trade, the department of state which controls the patent office, presented PATENT LAW REFORM, CMD. 6000, at 1 (1975) to Parliament. The report stated that:

> Modern industrial economies assume a high level of technology. A capacity to take advantage of technical innovation will continue to be an important factor influencing British industry's competitiveness in world markets. But innovation is frequently expensive and the commercial risks can be high. The protection given by the patent system provides a stimulus to invention and innovation, encouraging industry to strike out along new lines. Nonetheless, the system must evolve in response to changing conditions if it is to make its full contribution to the health of the British economy.

Id.

32. *Id.*

> The government accepts most of the main recommendations of the Banks' Committee and intends to introduce legislation during the next Parliamentary Session revising the patent system:
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> (i) so that it is in tune with modern trends and sufficiently flexible to accommodate future changes in technology;
> (ii) to streamline procedures for obtaining patents;
> (iii) to establish a Court specially equipped to hear patent cases;
> (iv) to take account of international developments in which successive British Governments have played a leading part in the interest of our industry and commerce.

Id.

33. Cooper, *The Patent System and the 'New Biology,'* 8 RUTGERS J. COMPUTERS, TECH. & L. 1 (1980) [hereinafter cited as Cooper]. Recent developments abroad reflect the tendency of other nations to promote technology through patenting systems. The German Patent System experienced expansive interpretation of its 1877 definition of patentable subject matter. The original definition was interpreted as a teaching of a technical character employing physical and chemical means of a predictable nature. This definition was unworkable for advances in science and technology. *Ex parte* Schreiner, 1 INT'L REV. INDUS. PROP. & COPYRIGHT L., 136, 137 (1970) (Budesgerichtshof 1969) (*"Rote Taube"/Red Dove*), *as cited in* Cooper, *supra*, at 29, n. 148.

The Japanese Patent office recently published "Guidelines Relating to Examination of Inventions of Microorganisms." English translation by A. Aoki & Associates, AIPPI J., Sept. 1979, at 151-55 as *cited in* Cooper; *supra*, at 31. Those guidelines indicate that country's intent to promote inventive technology. *Id.* For instance, "microorganisms" are defined to include "yeasts, molds mushrooms, bacteria, ac-

Britain's exportation of emergent technology significantly affected its international balance of payments.[34]

The United Kingdom later ratified several international patent conventions in order to broaden the scope of its own patent system.[35] One of the international conventions which Britain ratified was the Patent Co-operation Treaty.[36] That treaty established an international patent system for the initial filing and centralized searching for patent applications.[37] Great Britain also ratified the European Patent Convention (EPC),[38] which defines a uniform European patent law and procedure. By submitting a single application to the European Patent Office, one obtains a European patent, which has the effect of a national patent in all of the contracting states.[39] Thus, the successful patentee acquires a collection of national patents.[40]

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tinomycetes, algae, viruses, protozoa and the like, and for convenience, cultured tissues of animals and plants as well." *Id.*

The French government has signaled its intention to sponsor special programs in biotechnology, micro-electronics, and new sources of energy. Walsh, *French Government Bulletin on Science and Technology,* 213 SCI. 420 (1981). Under the Socialist regime of President François Mitterand, the government intends to use research and development as a major tool for achieving economic recovery. *Id.*

In a bid to keep up with developments abroad, India's Prime Minister, Indira Ghandi, recently announced that her government will establish a National Biotechnology Board to coordinate research in the field. Agarwal, *India Sets Up Biotechnology Board,* 93 NEW SCIENTIST 213 (1982). Government expenditures for biotechnology research will be approximately $15 million over the next three years. *Id.* Pakistan also recently established two centers to carry out research on genetic engineering. Frederick, *Pakistan Joins Gene Club,* 93 NEW SCIENTIST 488 (1982).

The Netherlands government recently decided to allocate 4 million guilders ($1.25 million) a year to support biotechnology research. Becker, *Going Dutch,* 295 NATURE 91 (1982).

The recent meeting of the Soviet Academy of Sciences stressed the biotechnology achievements in the U.S.S.R. Rich, *Keeping a Secret,* 295 NATURE 275 (1982).

34. Cooper, *supra* note 33, at 36.

35. CONVENTION OF THE GRANT OF EUROPEAN PATENTS (EUROPEAN PATENT CONVENTION), CMD. 5656 (1974); PATENT CO-OPERATION TREATY, CMD. 4530 (1970); and the CONVENTION FOR THE EUROPEAN PATENT FOR THE COMMON MARKET (COMMUNITY PATENT CONVENTION), O.J. EUR. COMM. (No. K. 17) (1976).

36. PATENT CO-OPERATION TREATY, CMD. 4530 (1970). Signators to the treaty were: Algeria, Brazil, Canada, Denmark, Finland, Federal Republic of Germany, Holy See, Hungary, Republic of Ireland, Israel, Italy, Japan, Norway, Phillippines, Switzerland, United Arab Republic, United Kingdom, United States and Yugoslavia. *Id.* at 42.

37. McFarlane, *supra* note 20, at 265. The drafters sought uniformity of the patenting procedure. *Id.*

38. CONVENTION OF THE GRANT OF EUROPEAN PATENTS (EUROPEAN PATENT CONVENTION), CMD. 5656 (1974).

39. Vittoria, *The Patents Act 1977,* 41 MOD. L. REV. 329, 324 (1978) [hereinafter cited as Vittoria]. The European Patent Office in Munich carries out the examination for patentability. *Id.*

40. Applicants have several objections to the application process, one of which was its relatively high cost (approximately $3500). Katona, *Beating the High Cost of European Patents,* 77 PAT. T.M. REV. 3 (1979). There exists both procedural and legal drawbacks as well. *Some Drawbacks to the European Patent,* 77 PAT. T.M. REV. 254 (1979). On a procedural level, the complexity and variations in terms present difficulties. Textual regulations are twenty to thirty times greater in length than regulations defining national systems. Third party opposition is more readily facilitated, and translation requirements further expand the chances of rejection on intricate procedural grounds. As a result, the duration of the European patent procedure is extremely protracted. *Id.*

The prime legal drawback to the European patent is its fragility. A European patent will not be

Great Britain's Patents Act 1977 is a modernization of that country's patent system and embodies its ratification of the EPC.[41] The Act repeals the entire Patents Act 1957,[42] as well as certain provisions of the Patents Act 1949[43] and the Copyright Act 1956.[44] The Act introduces several changes in the substantive law and procedure for obtaining patents.[45] Although the new Act does not explicitly determine the patentability of a synthesized virus, a discernible policy appears to favor granting patent protection in such cases.[46]

The Act introduces absolute standards of patentability which an applicant must satisfy before receiving a patent.[47] The standards also continue to apply after the grant of a patent.[48] In order to be patentable in Great Britain, an invention must be new, involve an inventive step, be capable of industrial appli-

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stronger than a national patent. This is due first to the absence of title before issue of the patent and second to the more limited scope of the European patent due to its vulnerability to third party opposition. *Id.* For a history of the developing harmonization of the European patent system, *see* Beier, *The European Patent System,* 14 VAND. J. TRANS. L. 1 (1981).

41. Part II (§§ 77-95) of the Patents Act 1977 provides for the assimilation of a European patent into the British system, such that a successful application made under either the Patent Co-operation Treaty or the EPC will become effective patents in the United Kingdom.

42. The Patents Act, 1957, 5 & 6 Eliz. 2, ch. 13.

43. The Patents Act, 1949, 12, 13 & 14 Geo. 6, ch. 87.

44. The Copyright Act, 1956, 4 & 5 Eliz. 2, ch. 47.

45. Some of the direct effects of the Patents Act 1977 are that: the term of the patent is extended from sixteen to twenty years (§ 25); third party attacks are confined to granted patents (§§ 72-74); a statutory basis is established for deciding whether an invention made by an employee belongs to that employee, or alternatively to his employer (§§ 39-43); secret use of an invention is no longer a ground for invalidating a subsequent patent for the same invention (§§ 86-88); the Patents Appeal Tribunal is replaced by a Patents Court which is part of the Chancery Division (§§ 96-108); and the overall Patent Office procedure is streamlined by early search and early publication provisions (§§ 17-21), thereby preventing the lengthy opposition proceedings possible under the Patents Act 1949.

46. The British Department of Trade sanctioned the policy of spurring investment in technology by way of patent protection. PATENT LAW REFORM, CMD. 6000 (1975). *See* note 31 *supra.*

47. Patents Act, 1977, ch. 37, § 1.

> 1. Patentable inventions
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> (I) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say —
>
> (a) the invention is new;
>
> (b) it involves an inventive step;
>
> (c) it is capable of industrial application;
>
> (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;
>
> and references in this Act to a patentable invention shall be construed accordingly.
>
> (2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of —
>
> (a) a discovery, scientific theory or mathematical method;
>
> (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
>
> (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
>
> (d) the presentation of information;
>
> but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such. . . .

Id.

48. H. BRETT, THE PATENTS ACT, 1977, 6-7 (1977) [hereinafter cited as BRETT]; McFarlane, *supra* note 20, at 266.

cation and not excludable from patentability by the statute.[49] The statute expressly excludes from patentability discoveries, scientific theories and mathematical methods.[50] These exclusions form a non-exhaustive list and closely follow prior law.[51]

The new definition of patentability in the Patents Act 1977 conforms to that of the EPC Articles 52 and 53. In order to ensure conformity with the EPC, the Act declares that the definition of patentability was designed to have, as nearly as practicable, the same effects as the corresponding provisions of the EPC.[52] The Act requires that the British Patent Office and British courts take judicial notice of the EPC, the Patent Co-operation Treaty and the Community Patent Convention, as well as decisions and opinions of convention courts.[53] Because of the harmonization sought between the British and international conventions,[54] the EPC Guidelines[55] will be discussed in interpreting British Patent Law. The Guidelines give general instructions as to the practice and procedure of the European Patent Office, and therefore are relevant when examining the Patents Act 1977.

B. *Conditions for Patentability in Great Britain*

Although there is no complete definition of "invention" in the Patents Act 1977, the meaning of the word is fundamental to the operation of the Act.[56] The Patents Act 1949 defined "invention" as any manner of new manufacture.[57] One group of commentators noted that that definition was in effect a definition of patentable subject matter.[58] That group also indicated that the definition of invention in the Patents Act 1977 appears to encompass anything devised by the inventor.[59] Nevertheless, the Act limits the grant of a statutory monopoly to

49. Patents Act, 1977, ch. 37, § 1(1).

50. Patent law theory has long held that discoveries of natural phenomenon are not patentable. P. ROSENBERG, PATENT LAW FUNDAMENTALS 13 (1979) [hereinafter cited as ROSENBERG].

51. Vittoria, *supra* note 39, at 326.

52. Patents Act, 1977, ch. 37, § 130(7).

53. Patents Act, 1977, ch. 37, § 91.

54. CHARTERED INSTITUTE OF PATENT AGENTS, C.I.P.A. GUIDE TO THE PATENTS ACT 1977, at 7 (1980) [hereinafter cited as C.I.P.A. 1977].

55. EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE (1979) [hereinafter cited as GUIDELINES]. The Guidelines were adopted in accordance with the EPC, art. 10. They are intended to cover the normal proceedings of the European Patent Office. Although the staff of the European Patent Office may depart from the Guidelines in exceptional cases, patent practitioners can expect the Office to act generally in accordance with the Guidelines. *Id.* at 1. The Guidelines do not have the binding authority of a legal text. *Id.*

56. C.I.P.A. 1977, *supra* note 54, at 7-8.

57. Patents Act, 1949, 12, 13 & 14 Geo. 6, ch. 87, § 101.

58. C.I.P.A. 1977, *supra* note 54, at 8. Prior to enactment of the Patents Act 1977, the Patent Office had a limited responsibility to ensure that patent applications fell within the concept of manner of new manufacture. No general standard of patentability existed, and the requirements for patentability were stricter only if the grant of a patent were opposed or its validity questioned in revocation proceedings. BRETT, *supra* note 48, at 6.

59. C.I.P.A. 1977, *supra* note 54, at 8.

patentable inventions in terms of novelty, inventive step and capability of industrial application. Section 1(5)[60] of the Act incorporates flexibility by allowing the Secretary of State for Trade to vary the list of exclusions in order to ensure that the patent system responds to the developments of science and technology.[61]

The three basic statutory conditions for patentability under the Patents Act 1977 are novelty, an inventive step and capability of industrial application.[62] An analysis of these three conditions indicates that the synthesized virus claim would meet these requirements.

1. Novelty

Novelty, as described under the Patents Act 1977,[63] is a function of "the state of the art," requiring the inventor to assert his originality against the "public

60. Patents Act, 1977, ch. 37, § 1(5).

61. *Id.* The Act states: "The subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament." *Id.*

62. *Id.* at § 1(1)(a)-(c).

63. *Id.* at § 2.

2. Novelty

(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say —

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.

(4) For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either —

(a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person —

(i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or

(ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it;

(b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor; or

(c) the disclosure was due to, or made in consequence of the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.

(5) In this section references to the inventor include references to any proprietor of the invention for the time being.

(6) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on

knowledge" of the world, without any restriction as to time or geography.[64] The Banks' Committee recommended such a novelty search, indicating that the closer the Patent Office's search approaches the whole field of the state of the art, the greater the presumption of the validity of the patent.[65] The standard of novelty under the Patents Act 1949 was the same as the test for infringement; a prior use in the United Kingdom would invalidate a claim.[66]

The Patents Act 1977 definition of novelty is based on EPC Articles 54, 55 and 89. Reference to the EPC Guidelines for Patent Offices provides insight as to the Act's novelty standard. The Guidelines indicate that a claim must be of a technical character. Specifically, the invention must relate to a technical field, involve a technical problem, and have definable technical features.[67] Such a definition accurately describes a synthesized virus because the virus' predictable features afford the scientist a solution to the problem of isolating research variables. Furthermore, the Guidelines explain that if the patentee can properly characterize the product without reference to the development process and if the

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the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

Id.

64. BRETT, *supra* note 48, at 8. The EPC, art. 54 and the Patent Co-operation Treaty, rule 31.1(a), both adopt a standard of absolute novelty. If the invention has been published or used anywhere in the world before the filing of an application, patenting of the invention is absolutely barred. The problem of concurrent applications is addressed in the Patents Act, 1977, ch. 37 § 2(3), which replaces the concept of "prior claiming" with the "whole contents" approach. Simply stated, the earlier of two similar patent applications will be deemed published for purposes of state of the art analysis.

Section 2(4) of the Act establishes the means by which non-prejudicial disclosures may be made by the patentee prior to filing. Because state of the art is construed broadly by the Patent Office, the patentee who provides information concerning his invention prior to filing should secure confidentiality in order to ensure novelty at the time of filing. For further discussion of what constitutes existence within the state of the art, *i.e.*, prior publication and earlier applications, see GUIDELINES, *supra* note 55, at 257-64. For further discussion concerning the extent to which patent examiners would search the prior art, *see id.* at 126-31.

65. THE BRITISH PATENT SYSTEM: REPORT OF THE COMMITTEE TO EXAMINE THE PATENT SYSTEM AND PATENT LAW, CMD. 4407, at 69.

66. The Patents Act, 1949, 12, 13 & 14 Geo. 6, ch. 87, §§ 32, 50. In *The British Thomson-Houston v. Metropolitan-Vickers* (1928) R.P.C. 1, 22, the Royal Patent Court stated that to deprive the claim of novelty, a prior use must have dealt with the same problem and achieved the same result.

67. GUIDELINES, *supra* note 55, at 247.

Section 1(3)(b) of the Patents Act 1977 excludes from patentability any variety of animal or plant or any essentially biological process for their production, not being a microbiological process or the product of such a process. The Chartered Institute of Patent Agents has indicated that the term plant or animal varieties might include some microorganisms; "hence the position as to claims to microorganisms *per se* is not clear, but microorganisms (as well as inanimate products) when produced by a microbiological process can be patented." C.I.P.A. 1977, *supra* note 54, at 11. The Institute further notes that the term microbiological process may be defined by the extent to which technical intervention by man exists in the process. *Id.* There is a positive correlation between the extent of technical intervention by man in the essentially biological process and the likelihood of patentability. Such a relationship is consistent with the underlying policy of a patent system to afford protection for man-made inventions.

The synthesized virus is a product of a microbiological process, but that process is one with significant technical intervention by man. Thus, the Patent Office should not exclude the synthesized claim from patentability.

product is new in the absolute sense of having no previously recognized existence, then the product may be patentable per se.[68] Hence, the claimant may be afforded an independent means by which to patent a synthesized virus.

Like discoveries, neither scientific theories nor mathematical methods are novel or patentable.[69] However, scientists who genetically manipulate a virus, so as to permanently alter its utility, produce a unique and novel product.[70] Such a product represents more than a mere theory or method. Therefore, the first of the three conditions for patentability is satisfied by the hypothetical virus claim.

Even in the event that the British Patent Office determines the virus to be an already existing form,[71] as an alternative one may obtain a patent for the new medical use of the known compound.[72] Under the Patents Act 1949,[73] an applicant was unable to obtain patent protection for known substances which had unexplained medical properties.[74] Because the substance was not novel, the patentees could not claim it was patentable per se.[75] Furthermore, processes for the medical treatment of human beings have never been patentable.[76] However, under the 1977 Act, an applicant now can obtain a patent for new medical properties of known substances which the patentee reveals for the first time.[77] The Act's provision corresponds to Article 54 of the EPC, and affords protection to the first applicant of a known substance or composition for human treatment, therapy, surgery or diagnosis.

Although the use of a synthesized virus could conceivably involve human

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68. GUIDELINES, *supra* note 55, at 249.

69. *Id.* An invention which utilizes such theories, however, is not necessarily non-patentable. This approach applies to programs for computers and presentations of information.

70. *See* notes 1-4 *supra.*

71. *See* notes 63-64 and accompanying text *supra.* An already existing form would be within the state of the art, and consequently excluded from statutory protection. GUIDELINES, *supra* note 55, at 247.

72. Patents Act, 1977, ch. 37, § 2(6).

73. The Patents Act, 1949, 12, 13 & 14 Geo. 6, ch. 87.

74. The Upjohn (Robert's) Application, (1977) R.P.C. 94, *as cited in* Vittoria, *supra* note 39, at 326 n.18. The applicant's specification included claims to a method of reducing gastric secretion in mammals by the systematic administration of certain compounds. The Patents Appeal Tribunal ruled that, under The Patents Act, 1949, a method of treatment of a human ailment with a known substance is not an invention.

75. *Id.* at 326 n.18.

76. *Id.*

77. Patents Act, 1977, ch. 37, § 2(6). Thus, under the old law, if the use of trundleamine, known for the treatment of diabetes, was discovered, a later discovery that it is an effective anti-malarial agent could not be patented. Organon's Application, (1970) R.P.C. 574, *as cited in* Vittoria, *supra* note 39, at 326, n.18. The patent court, in *Shering A.G.'s Application,* referred to the problem of the patentability of previously unexplained medical properties in dicta:

> It is no doubt sensible that a person who is able to produce a substance which, for example, would cure or prevent cancer, should, subject to safeguards, be offered a limited monopoly as a reward and the possibility of such a monopoly protection has undoubtedly resulted in enormous investment in research in the medical field. If this position is accepted, it is a little difficult to see why someone who by research effort devises a new method of using a known substance to achieve equally beneficial results should be denied patent protection.

Schering A.G.'s Application, (1971) R.P.C. 337, 341, *as cited in* Vittoria, *supra* note 39, at 326, n.18.

treatment, the virus claim probably would not fall within Section 2(6), which relates only to known substances or compositions. However, because a synthesized virus is a substance of previously unknown and unique composition, the virus claim should meet the initial patentability requirement of novelty.

2. Inventive Step

The second condition for patentability under the Patents Act 1977 is that the virus must involve an inventive step.[78] Inventive step and novelty are different criteria; novelty is a condition precedent to analysis for inventive step.[79] An invention may be new, yet be so obvious as to lack an inventive step.[80] Unless the invention is sufficiently original so as to contribute toward existing knowledge, it will not involve an inventive step sufficient to justify the grant of a patent.[81] The term "obvious," as used in the Act, means that which does not go beyond the normal progress of technology, but which merely follows plainly or logically by a person skilled in the art.[82] The Guidelines follow existing law and describe a "person skilled in the art" as one with the means and ability of an ordinary practitioner aware of the common general knowledge in the art. Nonetheless, the Guidelines stipulate that such a person is deemed to have "no imagination."[83]

According to this standard, patent authorities probably would not consider a synthesized virus to be "obvious." The recombinant nature of the synthesized virus goes beyond the normal progress of technology, and involves sufficient exercise of skill and creativity to carry it beyond the realm of the obvious.[84]

In conjunction with its analysis of obviousness, one group of commentators notes that an inventive step may arise by devising a solution to a known problem or it may arise by arriving at an insight into the cause of a known phenomenon.[85]

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78. Patents Act, 1977, ch. 37, § 3. "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)." *Id.* This section corresponds to EPC, art. 56.

79. GUIDELINES, *supra* note 55, at 264.

80. *Id.*

81. *Id.* Prior to the Patents Act, 1977, the Patent Office was required by law only to consider the novelty of patent applications, without regard to the existence of inventive step. Only if another patentee challenged the application was the applicant required to prove the existence of an inventive step. *Id.*

82. C.I.P.A. 1977, *supra* note 54, at 17. Inventive step analysis has received criticism. *See* Pagenberg, *The Evaluation of 'Inventive Step' in the European Patent System — More Objective Standards Needed,* 9 INT'L REV. INDUSTRIAL PROPERTY COPYRIGHT L. 1, 121 (1978).

83. GUIDELINES, *supra* note 55, at 267.

84. *See generally* notes 1-3 *supra,* describing the techniques used by researchers utilizing genetic engineering techniques.

85. C.I.P.A. 1977, *supra* note 54, at 17. The framers of the Guidelines stated that it is persuasive evidence of sufficient inventive step if the invention is of considerable technical value or provides a new technical advantage in fulfilling a "long felt want." GUIDELINES, *supra* note 55, at 275. Similar interpretation of the requirement was carried out by the Patent Office under the Patents Act 1949. *See, e.g.,* Hickton's Patent Syndicate v. Patents and Machine Improvements Co., Ltd., 26 R.P.C. 339, 347 (1909).

the synthesized virus meets both of these criteria. The virus may afford a solution to a research problem because it is a non-random variable.[86] For example, in disease research, a scientist could synthesize a virus in order to effectuate a known result, thereby providing the experimenter with insight into the cause of the disease. Once the Patent Office finds that an inventive step exists, it will determine the proposed patent's capability of industrial application.

3. Industrial Application

In addition to being novel and involving an inventive step, the virus also must be capable of industrial application to qualify for a patent under current British law.[87] An invention is capable of industrial application "if it can be made or used in any kind of industry, including agriculture."[88] The courts have broadly interpreted what activities constitute "industry."[89] The Patents Act 1977 does not require that the invention specifically be made or used in industry; the fact that the invention is capable of being used in industry is sufficient.[90]

One problem of industrial application which might confront the virus claim

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86. *See generally* note 2 *supra*. A non-random variable is also referred to as a constant. Scientific research is optimally based on the control of all relevant factors (or constants), except one. The greatest difficulty in disease research is isolating and then controlling variables in an effort to determine the actual cause and effect relationship under investigation. A genetically manipulated virus facilitates the establishment of a constant; previously, such a control was unavailable.

Gene splicing will enable researchers to acclerate the formidable task of identifying, locating and analyzing every one of the more than 100,000 genes found in a human cell. *See* notes 2-4 and accompanying text *supra;* and Golden, *Shaping Life in the Lab, Time,* March 9, 1981, at 50-59 (asserting that history will view technology in terms of decades: 1940's — plastics; 1950's — transistors; 1960's — computers; 1970's — microcomputers; and 1980's — genetic engineering).

87. Patents Act, 1977, ch. 37, § 4.

> 4. Industrial application
>
> (1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.
>
> (2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.
>
> (3) Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.

Id.

88. *Id.* at § 4(1). One of the differences between the Patents Act 1977 and the EPC concerns the specific wording relating to "industrial application." The Act requires an invention to be "capable" of industrial application, whereas EPC Article 52 requires an invention to be "susceptible" to industrial application. The framers of the Guidelines regard these terms as synonymous. GUIDELINES, *supra* note 55, at 9.

The interpretation given under the Patents Act, 1949 to the expression "manner of new manufacture" corresponds largely to the term "industrial application," according to one group of commentators. C.I.P.A. 1977, *supra* note 54, at 21. *See also* National Research Development Corporation's Application, (1961) R.P.C. 135.

89. C.I.P.A. 1977, *supra* note 54, at 20; GUIDELINES, *supra* note 55, at 255.

90. *Id.* The Guidelines note that very few inventions are excluded from patentability for lack of susceptibility of industrial application which are not already excluded by the statutory list relating to discoveries and the like. GUIDELINES, *supra* note 55, at 255.

arises in its use as a medical treatment. The Patents Act 1977 continues to exclude from patentability methods of treatment for humans and animals.[91] However, the Act does extend patentability to an invention relating to the "new medical use of a known substance."[92] Thus, the discovery of medical properties of a known substance which had not been previously recognized may now be patented.[93]

However, the patentability of the synthesized virus should not have to depend upon this expanded statutory limitation. As discussed earlier, the synthesized virus has its greatest utility in industrial application as a non-random variable in disease research.[94] This potential application of the synthesized virus should qualify it as "industrially applicable," as contemplated by the framers of the Act. Assuming the virus meets the previous requirements of novelty and inventive step, it will be patentable under Great Britain's Patents Act 1977.

III. BIOTECHNOLOGY PATENT LAW IN THE UNITED STATES

A. *Background of the U.S. Patent Law System*

U.S. federal patent law provides a constitutionally sanctioned[95] incentive system whereby the public marketplace determines any award for the inventor.[96] The patentee exchanges full and complete disclosure of how to make and use the claimed invention for the court-protected right to prevent others from the unlicensed production, use or sale of the particular invention or process for seventeen years.[97] This right even extends against those who discover the invention or process through independent research.[98] The award of patent protection

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91. *See* notes 72-77 and accompanying text *supra.*

92. Patents Act, 1977, ch. § 2(6).

93. *Id.*

94. *See* note 86 and accompanying text *supra.*

95. U.S. CONST. art. I, § 8, cl. 8 authorizes Congress "to promote the progress of Science and useful Arts by securing for Limited Times to Authors and Inventors the exclusive Right to respective writings and Discoveries."

96. *See* presentation by Chief Judge Markey at the Federal Judicial Center Workshop for District Judges, 80 F.R.D. 203, 205 (1979). Chief Judge Markey has said that "the patent system was the first freedom of information act" and the first "sunshine law." *Id.* The system is not based on profit. A patent on the unwanted is worthless in the marketplace. *Id.*

97. 35 U.S.C. § 154 (1970). Richey, *supra* note 12, at 376. An inventor in the United States does not have a common law right to a monopoly on his invention. Holstensson v. V-M Corp., 325 F.2d 109, 125 (6th Cir. 1963). An applicant must comply with congressionally established requirements as a condition to exercising such monopoly. *Id.*

Once the applicant complies with these requirements and is awarded a patent, "there are established limits which the patentee must not exceed in employing the leverage of his patent to control or limit the operations of the licensee." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 136 (1969). Such restrictions preclude the establishment of trade constraints and the acquisition of unreasonable royalty rates. Brulotte v. Thys Col., 379 U.S. 29 (1964).

98. *See* Cataphote Corp. v. Hudson, 422 F.2d 1290 (5th Cir. 1970). *Cataphote* involved an alleged infringement of a trade secret regarding a gas-fired furnace for producing microscopic glass beads. The court noted that a patent is totally exclusionary for the period granted, whereas the trade is protected only so long as competitors fail to duplicate it by legitimate, independent research. *Id.* at 1295.

dispels the fear of easy and inexpensive duplication of a patentee's invention by others[99] and encourages the patentee to publicize his invention.[100] Full disclosure in turn encourages innovation.[101] By awarding protection in the form of a patent, the statute increases the sum of useful knowledge available to the public.[102]

The primary purpose of the U.S. patent system is not to reward the patentee, but to advance the arts and sciences.[103] The Supreme Court has found a strong manifestation of congressional intent[104] to promote technology and the useful arts.[105] The Court has therefore construed the patent statutes liberally so as not to preclude the development of new and emergent technologies.[106] Such an approach enhances the probabilty of success for a synthesized virus claim under U.S. patent law.

B. *Requirements for Patentability in the United States*

The Patent Act of 1952[107] establishes the requirements one must satisfy in order to obtain a patent. Section 101 of the Act protects the invention or discovery of any new and useful process, machine or composition of matter, or any new and useful improvement thereof.[108] Like Great Britain,[109] the United

99. *See* Mandich, *Venetian Patents,* 30 J. PAT. OFF. SOC'Y 166 (1978), *as cited in* Cooper, *supra* note 33, at 37.

100. Richey, *supra* note 12, at 376. *See also* Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979). "The patent system is beneficial as it encourages and rewards inventions, stimulates new ideas and enables the public to use the invention after the patent expires. Further, ideas in general circulation remain available for unencumbered public use." *Id.*

101. Rosenberg, *supra* note 50, at 78.

102. Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 153 (1951). The case concerns the patentability of a combination patent claim for a grocer's cashier counter. The Court held that such a uniting of elements performs no additional or different function and is, therefore, an invalid patent claim. *Id.* at 152. *See also* text accompanying notes 12-15 *supra*.

103. Richey, *supra* note 12, at 376.

104. *See Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary,* 82d Cong., 1st Sess., 20 (1951) (statement of Charles J. Zinn, Law Revision Counsel, Comm. on the Judiciary). The last general revision of the patent laws was the Act of July 8, 1870. *Id. See generally* S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H. R. REP No. 1923, 82d Cong., 2d Sess. 6 (1952).

105. Graham v. John Deere Co., 383 U.S. 1, 6 (1966). "It is the duty of the Commission of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of Congress." *Id. See also* Diamond v. Chakrabarty, 447 U.S. 303 (1980). "In choosing such expansive terms as 'manufacture,' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction." *Id.* at 308, citing S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 6 (1952).

106. *See, e.g.,* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

107. The Patent Act of 1952, 35 U.S.C. §§ 101-103 (1970).

108. 35 U.S.C. § 101 (1970). "[W]hoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore. . . ." *Id.*

109. *See* note 69 and accompanying text *supra*.

States issues a patent for the application of a principle, but not for the principle itself.[110] "Composition of matter" and "process" are the two methods of patentability which are relevant to the synthesized virus claim.[111]

1. The Synthesized Virus as a Composition of Matter

In patent law, composition of matter includes chemical compounds and physical mixtures.[112] Just as a machine is a combination of parts, a composition of matter is a combination, union or association of ingredients.[113] Whether a machine is patentable may depend not only on the novelty of its components, but on the manner of their combination.[114] Similarly, the patentability of a composition of matter may turn not only on the novelty of its ingredients, but on the manner in which these ingredients are combined.[115] This combination must produce a unitary result.[116] Furthermore, the resulting product must exhibit a set of properties distinct from those possessed by its separate components.[117]

In light of these criteria, the Supreme Court, in *Diamond v. Chakrabarty,*[118] ruled upon the patentability of a man-made microorganism as a composition of matter. This case raised two issues. The primary issue involved the patentability

110. Tilgham v. Proctor, 102 U.S. 707 (1880). The issuance of patent for the principle itself would have the effect of banning all further uses of the scientific principle. The unpatentability of products of nature is a distinction created by the British Parliament and implicitly retained in current patent law. Statute 21 James I, ch. 3 (1623).

111. A third method of analysis, manufacture, is not as relevant as the composition of matter or process analyses are to the synthesized virus claim. The term "manufacture" is actually shorthand for article of manufacture and is derived from the English Statute of Monopolies, which speaks of "any manner of new manufactures." The Statute of Monopolies, 1623, 21 Jac. 1, ch. 3. U.S. law has given a more restrictive construction to the term manufacture as a term of art than has British law, and excludes that which is within the ambit of other statutory classes of inventive subject matter. For instance, a court has held that the manufacture of a new product does not depend upon novelty of the process, but may result from an appropriate (and new) selection of the composite ingredients. General-Tire and Rubber Company v. Watson, 184 F. Supp. 344, 351 (D. D.C. 1960). Excluded from the term manufacture are articles whose appearance, properties, function, form, shape or size has been only negligibly altered by a manufacturing process whereby the essential character of the article remains a product of nature. ROSENBERG, *supra* note 50, at 78.

112. ROSENBERG, *supra* note 50, at 78.

113. *Id.* A chemical element is a combination of subatomic particles such as protons, electrons and neutrons.

114. *Id.* A novel combination of elements which cooperate with each other so as to produce a new and useful result is patentable. Dal-Bac (Pty.), Ltd. v. Firma Astorwerk Otto Berning & Co., 244 F. Supp. 516, 523 (S.D.N.Y. 1965).

115. ROSENBERG, *supra* note 50, at 78.

116. *Id.* A unitary result forms a complete, united whole. *Id.*

117. *Id.* at 79.

118. Diamond v. Chakrabarty, 447 U.S. 303 (1980). Ananda Chakrabarty filed a patent application in 1972 which described a process to create a new genetically engineered strain of Pseudomonas aeruginosa capable of degrading liquid hydrocarbons. The application was assigned to the General Electric Company. The strain was unique because it could stably maintain four different plasmids not naturally found therein. *Id.* Acting in harmony, these plasmids degrade four different crude oil components and, as a result, can be effective in combatting oil spills and providing nutrients for aquatic life.

of a living microorganism created in a laboratory through genetic engineering. Implicitly, the case also determined the extent to which the Court would recognize the patent system as a means of promoting technical innovation.

In *Chakrabarty,* a patent examiner had rejected the patent claim for the microorganisms on the ground that living things are not patentable subject matter under Section 101.[119] The Supreme Court disagreed. The Court ruled that Congress must define the limits of patentability, and that courts should therefore give patent laws a wide scope.[120] The Court had previously cautioned other courts not to read into patent laws limitations which the legislature had not expressed.[121] In its interpretation of the statute, the Court found that the statute did not necessarily preclude living things from patentability.[122] With respect to the alleged hazards of recombinant DNA research,[123] the Supreme Court recog-

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119. In re Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978). The patent examiner approved the claim for a method of production and innoculation of the microorganisms, but rejected the claims for the genetically created bacteria strains. Chakrabarty appealed to the Patent Office Board of Appeals, which affirmed the initial decision, holding that the new bacteria were statutorily unpatentable material, rather than unpatentable as products of nature. The Court of Customs and Patent Appeals later reversed, relying on an earlier finding of patentability of living matter. In re Bergy, 503 F.2d 1031 (C.C.P.A. 1977).

120. Diamond v. Chakrabarty, 447 U.S. 303 (1980) (Brennan, White, Marshall and Powell, dissenting).

The history of the *Chakrabarty* case is noteworthy because of its complexity and impact. The Supreme Court had a petition for a writ of certiorari in a case which also involved issues of genetic engineering and patentability. Parker v. Bergy, 438 U.S. 902 (1978). The Court remanded *Bergy* to the Court of Customs and Patent Appeals for further consideration. The Patent Office therefore petitioned the Court of Customs and Patent Appeals to vacate its *Chakrabarty* decision. The Court of Customs and Patent Appeals then consolidated *Chakrabarty* and *Bergy* for reconsideration, and thereafter reaffirmed its earlier judgment that the claims were within statutory subject matter. Application of Bergy, 596 F.2d 952, 957 (C.C.P.A. 1979). The opinion was the lengthiest ever rendered by that court. The Supreme Court granted the government's petition for a writ of certiorari, but subsequently dismissed the case as moot when Bergy cancelled the disputed claim in his patent application. Parker v. Bergy, 444 U.S. 924 (1980). This dismissal left only *Chakrabarty* for the Court's consideration. Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

121. 447 U.S. at 308, *citing* United States v. Dublilier Condenser Corp., 289 U.S. 178, 199 (1933).

122. 447 U.S. at 313.

123. Some of the alleged hazards include the escape of carcinogenic research microorganisms from the laboratory (rapidly reproductive in community water supplies) and the creation of genetically modified mammals. Golden, *Shaping Life in the Lab, Time,* March 9, 1981, at 50-59. One observer notes, however, that the "extreme views heard at the height of the debate were groundless." Singer, *Recombinant DNA Revisited,* 209 SCI. 1318 (1980).

> The development of the genetic engineering techniques . . . was greeted, over the past decade, with both excitement and alarm. The possible benefits of the techniques were obvious, but some people felt there was reason for concern. Biologists called for an evaluation of the possible hazards of this research; the result was an unprecedented national and international effort in which the public governments and the scientific community joined to monitor research activities. New knowledge about the properties of genes and the behavior of the bacteria used in this work (usually *Escherichia coli*) has led to a steady lessening of these concerns and to a relaxation of the guidelines that once restricted such experiments. In retrospect, with the advantage of hindsight, the concerns about hypothetical hazards seem to have been unwarranted. We know of no adverse effects from this research. The great potential of the new techniques, both in promoting the growth of basic knowledge and in making possible the

nized its lack of competency to rule upon these social policy issues,[124] stating that Congress and the executive branch should more properly decide such issues.[125] By holding that the genetically engineered microorganisms in *Chakrabarty* were patentable, the Court implicitly signalled its intent to regard the patent system as a statutorily created means to promote scientific development.[126] Furthermore, the Court opened the door for the patentability of other biotechnological advances.

The Supreme Court's expansive view of the patent system favors the potential patentability of a synthesized virus under a composition of matter analysis. Although scientists do not agree as to whether or not a virus is a living entity,[127]

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synthesis of products of direct benefit to society, is much closer to realization than seemed likely only a few years ago.

Gilbert & Villa-Komaroff, *Useful Proteins from Recombinant Bacteria*, SCI. AM., Apr., 1980, at 90.

124. 447 U.S. at 317. The Court recognized the impropriety of judicial attempts to regulate the course of scientific research, and stated that resolution of such issues must rest with Congress. Even if recombinant DNA organisms are potentially dangerous, that danger would not warrant the denial of patent protection. The grant of a patent does not give the patentee the right to practice his invention. Rather, the patentee has the right to exclude others from practicing it without his permission. *Id.* Further the patentee must produce and market a patented invention in accordance with the law. Thus, the conferral of the patent right does not eliminate the need for compliance with safety legislation. Cooper, *supra* note 33, at 34.

125. 447 U.S. at 317. The Court invited Congress to review its decision. *Id.* Congress has considered various bills on this subject, but has yet to enact any statute that would affect recombinant research. A number of local municipalities and states, however, have enacted legislation controlling the kinds and scope of experiments that can be conducted. *E.g.*, Cambridge, Mass. Code art. II § 11.7 (1977); Borough of Princeton, N.J., Code Ch. 26A, § 1 (1978); Amherst, Mass., By-Laws art. III, § 10 (1978); Berkeley, Cal., Ordinances No. 5010-N.W. (1977); *see also* N.Y. PUB. HEALTH LAW § 3220 (McKinney 1978), MD. PUB. HEALTH CODE ANN. § 898 (1977).

The National Institutes of Health (NIH) has achieved the most pervasive control of DNA experimentation in its promulgation of the NIH Guidelines for Recombinant DNA Research (Guidelines or Rules), 45 Fed. Reg. 6724 (1980), amended at 45 Fed. Reg. 25367 (1980) and at 45 Fed. Reg. 50524 (1980). Traditionally the NIH functions as a research-oriented government agency. Since promulgation of the NIH Guidelines, however, the NIH apparently has begun to assume a more regulatory function in the control of DNA experimentation, although interestingly enough, it has no staff to monitor compliance.

Many experts agree that a strong federal presence in regulating recombinant DNA research is desirable. However, other observers argue that the guidelines should be voluntary because little evidence exists that there are hazards involved in such research. Dr. Paul Berg of Stanford University, for example, one of the three signatories of the letter which originally suggested a moratorium on recombinant DNA research, wrote that he believed the guidelines "are now dispensable." Dickson, *DNA Panel Has Second Thoughts*, 295 SCI. 447 (1982). *See also* Berg, *Dissections and Reconstructions of Genes and Chromosomes*, 213 SCI. 296 (1981).

126. By assuring patent protection, the patent scheme stimulates research for further development of useful technologies, such as genetically-engineered microorganisms. By promoting use of the patent system, the statute assures the public disclosure of the results of the research. The disclosure of such research should not only allay fears regarding genetic engineering, but also allow the public and Congress to identify those areas where prohibitions may be advisable. F. Fowler, *Patenting Microorganisms*, 30 DRAKE L. REV. 635, 647-49 (1980-81).

127. Common attributes of a living organism include: cellular organization; ability to derive energy from sources in the environment; motility; responsiveness to change in environmental conditions; and capacity to replicate. S. LURIA & J. BARNELL, JR., GENERAL VIROLOGY, 3 (1969) [hereinafter cited as LURIA & BARNELL].

this factor is not determinative in establishing patentability, as indicated by the Supreme Court in *Chakrabarty*.[128] Instead, it is compliance with statutory criteria that determines patentability.[129]

Viruses are chemically definable entities, whether existing inanimate in a test tube or functioning within a living cell.[130] The capability of viruses to be either animate or inanimate is not the critical point, however. Instead, the focus in on the constituent elements of a synthesized virus which combine to form a "composition of matter." This synthesis of previously unrelated elements meets the requirements of patentability as composition of matter.

2. The Synthesized Virus as a Process

The analysis of the virus as a process under Section 101 is more complex than the composition of matter analysis. Patents for compositions of matter are distinct from patents for the process resulting in the production of matter.[131] Patents for the former, if properly described, may exist independent of patents for the latter.[132] Due to the constraints of language, the process of making a product sometimes defines the product. These products are "products-by-process."[133] The process, not the product, therefore, is the defined invention.[134]

A process is an act or series of acts which transforms and reduces the subject matter to a different state or thing.[135] A process patent is therefore one which treats certain materials to produce a certain result.[136] Although any set of steps may properly be labeled a process, Section 101 limits the granting of patents to *invented* processes.[137]

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128. 447 U.S. at 313.

129. *Id.* Once shown to be within the ambit of the statutory requirements, patentability is established. *Id.* at 310.

130. PELCZAR, *supra* note 19 at 17.

131. Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245, 254 (1928). A process consists of an act, operation, or step (or series of steps) performed upon specified subject matter to produce a physical result. Under the Patents Act, any combination of physical or manipulative steps may comprise a process. ROSENBERG, *supra* note 50, at 73-74.

132. ROSENBERG, *supra* note 50, at 73-74.

133. General Foods Corp. v. Carnation Co., 411 F.2d 528, 530 (7th Cir. 1969), *cert. denied* 396 U.S. 440 (1969).

134. *Id.*

135. ROSENBERG, *supra* note 50, at 78. *See also* Holland Furniture Co. v. Perkins Glue Co., 277 U.S. at 254.

136. Phillips Petroleum Co. v. Sid Richardson Carbon and Gasoline Co., 416 F.2d 10, 11 (5th Cir. 1969). The court reaffirmed the doctrine of equivalence, whereby the patentee is protected from another's adoption of a process "that operates in substantially the same manner and under the same physical laws to produce the same result as that of the patented process." *Id. See also* Kemart Corp. v. Printing Arts Research Laboratories, Inc., 201 F.2d 624, 629 (9th Cir. 1953).

137. In re Sarkar, 588 F.2d 1330, 1333 (C.C.P.A. 1978). The court denied a patent claim for a process of constructing a mathematical model of a waterway, holding that sets of steps conducted entirely by nature are not subject to patenting. *Id.* In essence, an "invented" process must be one which is the result of some degree of human intervention. A process which is entirely a function of natural steps is not patentable. *Id. See also Chakrabarty,* 447 U.S. at 309.

Most of the recent litigation concerning the patentability of processes involves computer and mathematical patent claims.[138] Opponents of such applications stress that products of nature, such as algorithms,[139] are excluded statutorily from patentability.[140] Opponents of the synthesized virus claim could analogize a synthesized virus to an inert receptacle, or mere description, of genetic information, which is unpatentable.[141] The courts' determination of statutory subject matter focuses on whether a mathematical algorithm, formula or method of calculation is the basis for a process claim.[142]

None of these is the basis for the synthesized virus claim. The synthesized virus is a product of the series of steps known as genetic engineering or recombinant DNA — an "invented process" pursuant to Section 101. Genetic engineering involves the alteration of an organism's genetic code.[143] Because this process may

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138. *See, e.g.,* Parker v. Flook, 437 U.S. 584 (1978). In *Flook,* the Supreme Court held a mathematical formula unpatentable, stating that the process itself, not merely the mathematical algorithm under consideration, must be new and useful. The Court considered novelty unimportant in the decision to grant a patent. *See also* Diamond v. Diehr, 450 U.S. 175 (1980) (relating to a mathematical calculation for transforming raw, uncured synthetic rubber into a different state); Matter of Application of Bradley, 600 F.2d 807 (C.C.P.A. 1979) (patent denied for "Switch System Base Mechanism," relating to altering information in the computer's system base); Application of Maucorps, 609 F.2d 481 (C.C.P.A. 1979) (patent denied for computer-implemented model of sales organization); Application of Walter, 618 F.2d 758 (C.C.P.A. 1980) (patent denied for algorithm relating to seismic prospecting and surveying); and Arshal v. United States, 621 F.2d 421 (Ct. Cl. 1980) (pertaining to a directional computer for aircraft flight control and directed toward a vectorial data processing system for extracting or prescribing directions and the rates of change from given input vectors).

139. An algorithm is a mathematical formula or computational method. The Supreme Court's definition of an algorithm is "[a] procedure for solving a given type of mathematical problem." Gottschalk v. Benson, 409 U.S. 63, 65 (1972).

140. *Flook,* 437 U.S. at 593. *See also* Gottschalk v. Benson, 409 U.S. 63 (1972).

141. The Court stated in *Flook* that a formula which merely describes a natural phenomena is unpatentable. Hence, the relationship described by $E\text{-}mc^2$ is not patentable. Nonetheless, an inventive application of this formula may be patented. *Flook,* 437 U.S. at 594. Analogizing this approach to that of a synthesized virus, opponents of patentability would argue that such a virus is nothing more than a genetic formula. However, the information represented by the virus' genetic code of recombinant DNA is far more than a mere mathematical representation. The unique arrangement of the genetic structure is unlike any other naturally-occurring virus, and was created by an inventive concept. On the other hand, a description of a regular virus contains nothing patentable; it is completely analogous to a formula of a natural phenomenon.

142. *See* In re Diehr v. Lutten, 203 U.S.P.Q. 44 (1979). The case involved the subject matter patentability of a computer program process. The Court of Customs and Patent Appeals allowed the claim, stating:

> The Court's holding in *Flook* was "very simply" stated: "[O]ur holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101." *Id.* n. 18. As in *Benson,* this holding has nothing to do with computers or computer programs per se.
>
> This, as we perceive it, is the direction which has been given us by the Supreme Court. Until the Court directs us otherwise, we continue to disagree with the notion that a claim may be rejected as nonstatutory merely because it involves a computer program or is computer-related. As far as we are concerned, claims may be rejected under § 101 because they attempt to embrace only a mathematical formula, mathematical algorithm, or method of calculation but not merely because they define inventions having something to do with a computer.

Id. at 50. *See also* note 138 *supra.*

143. *See* notes 1-4 and accompanying text *supra.*

occur at random in nature,[144] *e.g.*, by radiation, some opponents of the *Chakrabarty* claim[145] regarded this alteration aspect to be fatal to patentability.[146] However, when a scientist synthesizes a virus through the genetic engineering process, the resulting organism should be patentable for at least two reasons. First, "a claim does not recite a nonstatutory subject matter merely because an element or a step, when considered out of the context of the rest of the claim, is found to contain a[n unpatentable] natural law or mathematical formula."[147] The natural law premise that an organism is unique due to its genetic structure underlies the genetic engineering process,[148] and thus, the synthesized virus embodies its recombined DNA structure. Nonetheless, simply because this natural law forms a step in the process of genetic engineering does not render the process unpatentable.[149] Second, although the basic biotechnological methods involved in genetic engineering are not unique,[150] their application to a virus is unique[151] and, therefore, warrants patentability as a process. As of yet, synthesis of a virus with which to "infect" a bacterium is one aspect of biotechnology with which patent law has not yet dealt, and thus is innovative.

3. Novelty

In addition to the requirement that a patent application satisfy the composition of matter or process analyses under Section 101, Section 102 imposes a requirement of novelty.[152] This requirement should present little problem for

144. Cohen and Shapiro, *Transposable Genetic Elements*, SCI. AM., Feb., 1980, at 40-41. The major discovery in the biological sciences during this century has been the essential nature of DNA as the genetic blueprint of life. PELCZAR, *supra* note 19 at 218.

145. Respondent's Brief, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

146. *Id.*

147. In re Johnson, 589 F.2d 1070, 1077 (C.C.P.A. 1978). In examining a claim involving methods for removing undesirable signal noises from seismic data, the court held that the claim was not rendered nonstatutory by the fact that the process at issue was implemented by a nonstatutory computer system. *Id.*

148. EBERT, *supra* note 19 at 12.

149. In re Sarkar, 588 F.2d 1330, 1333 (C.C.P.A. 1978). If the genetic engineering process were entirely composed of steps performed in nature, it would not be subject to patenting.

> "Sets of steps conducted entirely by nature are not subject to patenting; they are not invented by man. Sets of steps occurring only in the mind have not been made subject to patenting because mental processes are but disembodied thoughts, whereas inventions which Congress is constitutionally empowered to make patentable are tangible embodiments of ideas the useful or technological arts."

Id.

150. *See Chakrabarty*, 447 U.S. at 309.

151. *See* text accompanying note 19 *supra*.

152. 35 U.S.C. § 102 (1970).

> § 102. Conditions for patentability; novelty and loss of right to patent.
> A person shall be entitled to a patent unless —
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

the virus patent application. The patentee only needs to establish that others have not known of, used or patented the synthesized virus in the United States or in a foreign country prior to submission of a patent application.[153]

The requirement of novelty extends to foreign applicants. When a corresponding foreign application[154] is filed more than twelve months before the filing of the application in the United States, Section 102(d) bars the granting of a United States patent if the foreign country patented the invention before the U.S. filing date.[155] The filing of an invention in Great Britain, for Section 102(d) purposes, is the date the British patent is granted.[156]

Since a virus is a receptacle (or description) of information, some observers analogize the virus to other inventions which are unpatentable, such as mathematical formulae or algorithms.[157] If such discoveries of natural, informational and inert phenomena were patentable, this would preclude their use by others.[158] Furthermore, an algorithm merely reveals a relationship that has always existed.[159] Recognition of such an existing principle carries with it no rights to

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(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor certificate, by the applicant or his legal representative or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Id.

153. 35 U.S.C. § 102(a) (1970). Two commentators claim that the Patent Office standard for patentability has been reduced virtually to mere novelty; that old technology is repatentable via cosmetic change. Irons & Sears, *Patent Reexamination: A Case of Administrative Arrogation,* 1980 UTAH L. REV. 287, 289 (1980). Such an assertion is somewhat overstated. Recent decisions reveal the failure to reduce standards of patentability. *See, e.g.,* note 138 *supra.* Further, the standard of review in these decisions is that the existence of similar technology in the prior art precludes the granting of a claim.

154. In re Monks, 588 F.2d 308 (C.C.P.A. 1978). The case raised the issue of when an invention is deemed patented in Great Britain under 35 U.S.C. § 102(d). *Id.*

155. *Id.* at 309.

156. *Id.* The United States bars a patent if a foreign country patented, *i.e.,* granted or issued, the invention before the U.S. filing date. *Id.* at 310.

157. Weiss, *United States: Summary of Court of Customs and Appeals In Re Bergy and In Re Chakrabarty,* 18 I.L.M. 983, 985 (1979) [hereinafter cited as Weiss].

158. Examples of other unpatentable mathematical formulae include the speed of light and the force of gravity. Both formulae represent natural phenomena, are informational and are inert. Yet the applicable patent statute may utilize either formulae in a unique, inventive manner. Thus, the formulae are patentable. *See generally* Parker v. Flook, 437 U.S. at 593.

159. A natural phenomenon is never patentable. *Id.*

exclude others from its enjoyment. Patentable subject matter, on the other hand, must be novel, not merely previously unknown.[160]

The inert nature of a mathematical formula is not fatal to a patent application.[161] Even though a phenomenon of nature may be well-known, an inventive application of the principle is patentable.[162] Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.[163]

In terms of patentability analysis, a virus created in a biotechnology laboratory is closer to a genetically engineered microorganism than a mathematical formula.[164] Scientists have artifically introduced, through genetic engineering techniques, a plasmid which is habitually present in one species of microorganism into another species of microorganism, which does not normally carry out the same physiological activity.[165] The recipient microorganism becomes endowed with that new property, thereby potentially becoming more useful than the previously existing strain.[166] This procedure requires the scientist to identify microorganisms displaying a desired characteristic, isolate the plasmid containing the gene responsible for the characteristic, introduce the plasmid into the recipient microorganism and achieve compatibility and acceptability for the plasmid within the new microorganism.[167]

Each of the procedural steps which have been applied to microorganisms involves the successful execution of highly sophisticated laboratory techniques in order to achieve a virus exhibiting a desired characteristic not found in nature.[168] The successful completion of the process produces a virus which would

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160. ROSENBERG, *supra* note 50, at 13-14. Novelty is a requisite for patentability in both Great Britain and the United States. Patents Act, 1977, ch. 37 § 2; 35 U.S.C. § 102 (1970).

161. *Flook,* 437 U.S. at 594. The only novel feature on a method for which a patentee filed an application was a mathematical formula. On certiorari the Supreme Court held the formula unpatentable. The identification of a limited category of useful, though conventional, post-solution applications of the formula did not make the patent eligible for patent protection. A process is not unpatentable under 35 U.S.C. § 101 simply because it contains a law of nature or mathematical algorithm. However, the process itself, not merely the mathematics algorithm, must be new and useful. The novelty of the algorithm and its applications are not determining factors in the award of a patent. *Id.* at 588-90.

Congress resolved the *Flook* issue by enacting the Computer Software Copyright Act of 1980. Computer programs are included among writings to which the inventor may obtain exclusive rights. The effect of such protection will be the stimulation of investment in development of new programs and new software technology. Holden, *Briefing,* 211 SCI. 37 (1981).

162. *See, e.g.,* notes 137 & 159 *supra.*

163. *Flook,* 437 U.S. at 594.

164. A synthesized virus is a genetically engineered product, containing unique genetic information, with consequent unique application. *See* note 19 and accompanying text *supra.* A mathematical formula, representing a natural phenomenon, does not contain unique information, regardless of its application. *Flook,* 437 U.S. at 594. *See generally* note 161 and accompanying text *supra.*

165. Amicus curiae brief of American Society for Microbiology, Parker v. Chakrabarty, 447 U.S. 303 (1980).

166. *See* notes 2-8 and accompanying text *supra.*

167. *See* notes 1, 3, 4 & 8 *supra.*

168. *Id.*

be "new" within the statutory construction of Section 102. Unlike the "inert" algorithm, the new virus is a novel subject matter, and thus, the analysis underlying non-patentability of the algorithm is inapplicable to the virus. The virus claim, therefore, appears to meet the requirements of Section 102.

4. Nonobviousness

Section 103 of the Patents Act[169] is often the most difficult requirement of patentability to apply.[170] It requires that the claimed subject matter be nonobvious, at the time the invention was made, to a person having ordinary skill in the art to which the claimed subject matter pertains.[171] Section 103 frequently requires that the Patent Office make a complex factual analysis of the claims of the patent in light of the technology that existed at the time of the invention.[172]

Case law indicates that a synthesized virus claim would meet the Section 103 requirement of nonobviousness. U.S. courts have held that an invention is not patentable if a person of ordinary skill in the art could have created the invention.[173] The test is not whether the object is an improvement in the art or whether the object works better,[174] because an improvement in the art is not entitled to patent protection.[175] If the claim covers an invention that combines old and well-known elements, as does a synthesized virus claim,[176] one of the factors a court will look for in analyzing Section 103 nonobviousness is synergism, *i.e.*, that which results "in an effect greater than the sum of the several effects taken separately."[177] Courts also look, in considering patentability from a

169. 35 U.S.C. § 103.

> § 103. Conditions for patentability; non-obvious subject matter.
>
> A patent may not be obtained though the invention is not identically disclosed or described and set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Id.

170. *See* Charney, *Patent Infringement and Validity: A Guide for the General Practitioner*, 55 CALIF. STATE B.J. 202, 204 (1980).

171. 35 U.S.C. § 103 (1970). See Gershman and Scafetta, *Patents on Microorganisms*, 21 IDEA/J.L. & TECHNOLOGY 1 [hereinafter cited as Gershman and Scafetta] for strategic considerations when filing a patent claim for genetically engineered products.

172. *See, e.g.*, cases cited in note 138 *supra.*

173. *See, e.g.*, Airlite Plastics Co. v. Plastilite Corp., 526 F.2d 1078, 1082 (5th Cir. 1975), *cert. denied*, 425 U.S. 936 (1976).

174. *Id.*

175. Reinke Mfg. Co. Inc. v. Sidney Mfg. Corp., 594 F.2d 644 (8th Cir. 1978). The case dealt with slight modifications in stress design relating to an electrically driven circular irrigation system. *Id.* at 645. The court also found that the claim could not overcome the requisite nonobviousness when analyzed in terms of whether a hypothetical person skilled in the relevant art could have accomplished the same result. *Id.* at 648-52. *See also* Sakraida v. Ag Pro Inc., 425 U.S. 273, 281 (1976); Great A&P Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152-53 (1950).

176. *See* note 161 and accompanying text *supra.*

177. Anderson's Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 61 (1969).

nonobviousness analysis, for the possibility that the invention may solve a problem in a way not previously recognized.[178]

The synthesized virus, having a unique genetic structure, is useful in new areas of research.[179] Because such a virus consists of a genetic reconstruction, the Patent Office may require a showing of synergistic qualities. In that case, the claimant need only demonstrate that no other single virus or group of viruses is genetically capable of performing like the synthesized virus.[180] The claimant may do this by demonstrating that the synthesized virus solves a previously recognized problem of disease research.[181] The virus is capable of solving such a problem because the utility of a synthesized virus lies in its uniquely predictable nature.[182] It is this need for non-random variables in virology research that is the basis for the patentability of a synthesized virus.

IV. CONCLUSION

In contrast to the United States, Great Britian's patent system required nearly complete revision in order to handle the recent explosion in technical innovation. Whereas the Supreme Court was able to analyze emergent technology, such as genetic engineering, within the framework of existing patent law, British courts frequently found that that nation's patent system was insular and outdated.

During the last decade, lawmaking entities in both Great Britain and the United States were aware of developments in patent law beyond the arenas of Parliament and the Supreme Court. Great Britain's participation in European patent conventions afforded the nation access to a flexible and transnational patent scheme, one which Great Britain selectively incorporated into its Patents Act 1977. In ruling on the patentability of a genetically engineered microorganism, the Supreme Court in *Chakrabarty* was at the focus of a multitude of divergent sources of opinion. Some factions believe that life forms should not be patentable. They feel that such research should be halted, or at least not given

178. Solder Removal Co. v. U.S. International Commission, 582 F.2d 628, 635 (C.C.P.A. 1978). The court held the patent claim invalid because one skilled in the art, and having the prior art of record before him, would have found it obvious to utilize the procedure claimed in the patent application. *Id.* at 638.

In In re Goodwin, 576 F.2d 375, 377 (C.C.P.A. 1978), the court refused to recognize "obvious to try" rejections and noted that "obvious to try" is not the standard of 35 U.S.C. § 103 (1970). *See* also cases cited in notes 173 & 175 *supra.*

179. Mechanical purification and isolation has greatly advanced virology research, but, as in any other type of biochemical work, perhaps the single most important research aid is a reasonably convenient means for the bioassay of fractions. LURIA & BARNELL, *supra* note 127, at 3. *See also* notes 1-3 and accompanying text *supra.*

180. A group of viruses, representing the constituent genetic elements of the synthesized virus, may be similar to the claimant's genetically engineered virus, but synergistically the synthesized virus results "in an effect greater than the sum of the several effects taken separately." *Anderson's Black Rock Inc.*, 396 U.S. at 61.

181. *See* notes 1-7 and accompanying text *supra.*

182. *See* notes 1-7 & 88 and accompanying text *supra.*

impetus in the form of patent protection. Consequently, the patent system in the United States was also subject to reevaluation. The Court in essence determined that the patent system in the United States should continue to promote research and development.

The contemporaneous developments of patent law in Great Britain and the United States are less a result of coincidence and more a response to the rapid advances in innovation. One such advance which is at the leading edge of science, technology and public policy is biotechnology. In an attempt to meet successfully the rapid growth in science and technology, Great Britain enacted the Patents Act 1977. A new invention, which involves an inventive step and is capable of industrial application, qualifies for patent protection. The Patents Act 1977 incorporates broad language in order to assure maximal protection for innovators. The motivation underlying the Act is to encourage research and development of technologies beneficial to society. A biotechnologist who successfully synthesizes a virus, which provides a welcome degree of certainty in disease research, will receive patent protection. More importantly, society will benefit since patent protection will encourage further worthwhile research which might otherwise have been hampered, postponed or thwarted altogether.

In the United States, the Supreme Court in *Chakrabarty* recently gave an expansive interpretation to the Patent Act of 1952 and thereby further broadened the opportunity of patent protection for emergent technology. Whether examined via composition of matter or process claim, the hypothetical synthesized virus claim is patentable subject matter under the Patent Act of 1952. The claim also passes the tests of novelty and nonobviousness. As such, the claim is entitled to U.S. patent protection.[183]

In sum, the current patent systems in Great Britain and the United States provide the necessary incentive for the disclosure of patentable emergent technologies. This interface of science, technology and public policy results in society's net benefit of encouraging further worthwhile research which might otherwise have remained uninspired.

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183. Gershman and Scafetta, *supra* note 171, at 4.